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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR     | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|--------------------------|---------------------|------------------|
| 09/894,956   | 06/27/2001  | William Michael Lafferty | DIVER1280-14        | 7268             |
| 7590   | 10/20/2003  |                          | EXAMINER            |                  |
| Lisa A. Haile, J.D., Ph.D.<br>Gray Cary Ware & Freidenrich LLP<br>4365 Executive Drive, Suite 1100<br>San Diego, CA 92121-2133 |             |                          | FORMAN, BETTY J     |                  |
|  |             |                          | ART UNIT            | PAPER NUMBER     |
|  |             |                          | 1634                |                  |

DATE MAILED: 10/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b>       |  |
|------------------------------|------------------------|---------------------------|--|
|                              | 09/894,956             | LAFFERTY, WILLIAM MICHAEL |  |
| Examiner                     | Art Unit               |                           |  |
| BJ Forman                    | 1634                   |                           |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 12 May 2003 and 06 August 2003.

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1-10 and 44 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-10 and 44 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121

**Attachment(s)**

1)  Notice of References Cited (PTO-892) 4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_ .  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948) 5)  Notice of Informal Patent Application (PTO-152)  
3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3/03 . 6)  Other: \_\_\_\_\_

**FINAL ACTION**

***Status of the Claims***

1. This action is in response to papers filed 12 May 2003 in which claims 1 and 7-10 were amended, claims 11-43 were canceled and claim 44 was added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections under 35 U.S.C. 112, second paragraph; under 35 U.S.C. 102(b); and under 35 U.S.C. 103 in the Office Action dated 14 November 2002 are withdrawn in view of the amendments and new grounds for rejection.

All of the arguments have been thoroughly reviewed but are deemed moot in view of the new grounds for rejection resulting from the Information Disclosure Statement submitted 31 March 2003. New grounds for rejection are discussed below.

Claims 1-10 and 44 are under prosecution.

***Priority***

*Reiterated from the previous office action*

2. Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. However, parent applications 09/636,778 filed 11 August 2000; 09/098,206 filed 16 June 1998; and 08/876,276 16 June 1997 upon which priority is claimed do not provide adequate support under 35 U.S.C. 112 for claims 1-10 of this application. Specifically, the parent applications do not provide support for the instantly claimed screening apparatus comprising: plurality of capillaries held together in an array, interstitial material disposed between adjacent capillaries;

and one or more reference indicia formed within the interstitial material. Therefore, the effective filing date for instant Claim 1-10 is the filing date of parent application 09/444,112 i.e. 22 November 1999.

***Specification***

3. The amendment filed 12 May 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendment to paragraph 0006 recites “The apparatus further includes interstitial material disposed between adjacent capillaries in the array, and optionally, one or more reference indicia formed within the interstitial material”. The amendment adds “optionally” and deletes “within” thereby changing the definition of the apparatus. Applicant has not pointed to support in the originally filed specification for these changes and new definitions. Because the originally filed specification does not provide support for these amendments, the amendments introduce new matter into the disclosure.

Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 1-7 are rejected under 35 U.S.C. 102(a) as being anticipated by Kumar et al (WO 98/04920, published 5 February 1998).

Regarding Claim 1, Kumar et al disclose a sample screening apparatus comprising: a plurality of capillaries held together in an array (page 6, lines 1-8) wherein each capillary comprises at least one wall defining a lumen for retaining a sample (page 7, line 19-page 8, line 2); and interstitial material disposed between adjacent capillaries (i.e. cartridge comprising a frame for holding tubes in a spaced-apart manner (page 6, lines 1-8 and Fig. 3).

Regarding Claim 2, Kumar et al disclose the array wherein each capillary has an aspect ration of between 10:1 and 100:1 (i.e. inner diameter of about 1.0  $\mu\text{m}$  to about 1mm, and length of about 10m m to about 150 m m, page 26, lines 10-28).

Regarding Claim 3, Kumar et al disclose the array wherein each capillary has an aspect ration of between 20:1 and 100:1 (i.e. inner diameter of about 1.0  $\mu\text{m}$  to about 1mm, and length of about 10m m to about 150 m m, page 26, lines 10-28).

Regarding Claim 4, Kumar et al disclose the array wherein each capillary has an aspect ration of between 40:1 and 50:1 (i.e. inner diameter of about 1.0  $\mu\text{m}$  to about 1mm, and length of about 10m m to about 150 m m, page 26, lines 10-28).

Regarding Claim 5, Kumar et al disclose the array wherein each capillary has a length of between 5m m and 10 cm (page 26, lines 22-26).

Regarding Claim 6, Kumar et al disclose the array wherein the lumen of each capillary has an internal diameter of between 3 $\mu$  m and 500 $\mu$  m (page 26, lines 15-20).

Regarding Claim 7, Kumar et al disclose the array wherein the plurality of capillaries are held together by being fused to one another i.e. adhesively sealed to the cartridge thereby being fused to one another (page 66, lines 9-11).

6. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Dehlinger (U.S. Patent No. 5,763,263 issued 9 June 1998).

Regarding Claim 1, Dehlinger discloses a sample screening apparatus comprising: a plurality of capillaries held together in an array wherein each capillary comprises at least one wall defining a lumen for retaining a sample; and interstitial material disposed between adjacent capillaries (Column 7, line 50-Column 8, line 33).

Regarding Claim 2, Dehlinger discloses the array wherein each capillary has an aspect ratio of between 10:1 and 100:1 (i.e. 20-200 $\mu$  inner diameter and length of 0.5 to 3 cm, Column 8, lines 3-16).

Regarding Claim 3, Dehlinger discloses the array wherein each capillary has an aspect ratio of between 20:1 and 100:1 (i.e. 20-200 $\mu$  inner diameter and length of 0.5 to 3 cm, Column 8, lines 3-16).

Regarding Claim 4, Dehlinger discloses the array wherein each capillary has an aspect ratio of between 40:1 and 50:1 (i.e. 20-200 $\mu$  inner diameter and length of 0.5 to 3 cm, Column 8, lines 3-16).

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Regarding Claim 5, Dehlinger discloses the array wherein each capillary has a length of between 5m m and 10 cm (i.e. 0.5 to 3 cm, Column 8, lines 3-16).

Regarding Claim 6, Dehlinger discloses the array wherein the lumen of each capillary has an internal diameter of between 3 $\mu$  m and 500 $\mu$  m (i.e. 20-200 $\mu$  inner diameter, Column 8, lines 3-16).

Regarding Claim 7, Dehlinger discloses the array wherein the plurality of capillaries are fused together to form the array (i.e. bonded or fixed, Column 8, lines 17-27).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 8-10 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al (WO 98/04920, published 5 February 1998) in view of Winkler et al (U.S. Patent No. 5,677,195).

Regarding Claim 44, Kumar et al disclose a sample screening apparatus comprising: a plurality of capillaries held together in an array (page 6, lines 1-8) wherein each capillary comprises at least one wall defining a lumen for retaining a sample (page 7, line 19-page 8, line 2); and interstitial material disposed between adjacent capillaries (i.e. cartridge comprising a frame for holding tubes in a spaced-apart manner (page 6, lines 1-8 and Fig. 3). but they do

not teach the apparatus further comprises one or more reference indicia disposed within the interstitial material.

However, reference indicia within interstitial material of an array was well known in the art at the time the claimed invention was made as taught by Winkler et al who specifically teach that reference indicia are essential for consistent and precise positionally addressable array construction and use (Column 18, line 51-Column 19, line 24). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the reference indicia of Winkler et al in the array of capillaries taught by Kumar et al to thereby place reference indicia within the interstitial material of the capillaries for the expected benefits of consistent and precise screening apparatus construction and use as taught by Winkler et al (Column 18, line 51-Column 19, line 24).

Regarding Claims 8 and 9, Kumar et al do not teach reference indicia wherein one or more reference indicia formed at intervals (Claim 8) and formed at edges (Claim 9). However, reference indicia within interstitial material of an array was well known in the art at the time the claimed invention was made as taught by Winkler et al (Column 18, line 51-Column 19, line 24). And Winkler et al specifically teach arrays comprising reference indicia at formed at array intervals (i.e. local) and at edges (i.e. global) wherein the local and/or global indicia are essential for exact positioning and detecting of array addresses (Column 19, lines 4-39). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the local and/or global reference indicia of Winkler et al in the array of capillaries of Kumar et al and to place the reference indicia at intervals and/or at edges of the array for the expected benefits of consistent and precise array construction and use as taught by Winkler et al (Column 18, line 51-Column 19, line 24).

Regarding Claim 10, Kumar et al teach the capillaries comprises glass (page 26, lines 6-9) but they do not teach the array comprises reference indicia formed of glass. Winkler et al teach a similar array wherein the array comprises glass (Column 6, lines 49-60 and Column

14, lines 45-55) and they teach the array comprises reference indicia (Column 19, lines 4-24). Therefore, the reference indicia of Winkler are formed of glass as claimed. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the glass capillaries of Kumar et al by forming reference indicia on the array as taught by Winkler et al for the expected benefits of consistent and precise array construction and use as taught by Winkler et al (Column 18, line 51-Column 19, line 24).

9. Claims 8-10 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dehlinger (U.S. Patent No. 5,763,263 issued 9 June 1998) in view of Winkler et al (U.S. Patent No. 5,677,195).

Regarding Claim 44, Dehlinger teaches the sample screening apparatus comprising: a plurality of capillaries held together in an array wherein each capillary comprises at least one wall defining a lumen for retaining a sample; and interstitial material disposed between adjacent capillaries (Column 7, line 50-Column 8, line 33) but they do not teach the apparatus further comprises one or more reference indicia disposed within the interstitial material.

However, reference indicia within interstitial material of an array was well known in the art at the time the claimed invention was made as taught by Winkler et al who specifically teach that reference indicia are essential for consistent and precise positionally addressable array construction and use (Column 18, line 51-Column 19, line 24). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the reference indicia of Winkler et al in the capillary array of Dehlinger thereby placing reference indicia within the interstitial material of the array for the expected benefits of

consistent and precise array construction and use as taught by Winkler et al (Column 18, line 51-Column 19, line 24).

Regarding Claims 8 and 9, Dehlinger teaches their array of subarrays provides a positionally addressable device (Column 4, line 65-column 5, line 4) but they do not teach the interstitial material comprises one or more reference indicia formed at intervals (Claim 8) and formed at edges (Claim 9). However, reference indicia within interstitial material of an array was well known in the art at the time the claimed invention was made as taught by Winkler et al (Column 18, line 51-Column 19, line 24). And Winkler et al specifically teach arrays comprising reference indicia at formed at array intervals (i.e. local) and at edges (i.e. global) wherein the local and/or global indicia are essential for exact positioning and detecting of array addresses (Column 19, lines 4-39). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the local and/or global reference indicia of Winkler et al in the positionally addressable array of Dehlinger and to place the reference indicia at intervals and/or at edges of the array for the expected benefits of consistent and precise array construction and use as taught by Winkler et al (Column 18, line 51-Column 19, line 24).

Regarding Claim 10, Dehlinger teaches the array wherein capillary array comprises glass (Column 7, lines 40-47; Column 8, lines 34-44; and Column 13, line 56-Column 14, line 32) but they do not teach the array comprises reference indicia formed of glass. Winkler et al teach a similar array wherein the array comprises glass (Column 6, lines 49-60 and Column 14, lines 45-55) and they teach the array comprises reference indicia (Column 19, lines 4-24). Therefore, the reference indicia of Winkler are formed of glass as claimed. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the glass array of Dehlinger by forming reference indicia on the array as taught by Winkler et al for the expected benefits of consistent and precise array construction and use as taught by Winkler et al (Column 18, line 51-Column 19, line 24).

**Response to Applicant's comments**

10. Applicant's arguments regarding the previous rejection over Millstein is deemed moot in view of the withdrawn rejection.

Regarding Dehlinger, Applicant argues that Dehlinger neither discloses nor suggests that the synthesized molecule can be retained within capillaries by capillary forces. The argument has been considered but is not found persuasive because molecule retention and/or capillary forces are not limitations in the instant claims. Therefore the argument is not relevant to the limitations recited in the instant claims. However, it is noted that the molecules synthesized by Dehlinger are retained in the capillaries (Column 18, lines 5-57).

Applicant further argues that Dehlinger fails to suggest that the capillaries are dimensioned for capillary loading with cells for incubation within the tubes in the presence of a substrate and/or for interaction of the substrate and a recombinant clone or cell to produce a signal. Again, the argument has been considered but is not found persuasive because capillary loading, cell incubation, substrate and/or substrate interactions are not limitations in the instant claims. Therefore the argument is not relevant to the limitations recited in the instant claims.

Regarding the combination of Dehlinger and Winkler, Applicant argues Winkler does not cure the deficiencies of Dehlinger because that there is no suggestion in Winkler of an array of tubes dimensioned to load and retain by capillary action, an analyte. The argument has been considered but is not found persuasive for the reasons stated above regarding Dehlinger i.e. because molecule retention and/or capillary forces are not limitations in the instant claims, the argument is not commensurate in scope with the instant claims.

Applicant further argues that the Office has provided no reasoning that would support an argument that Winkler suggests how to modify the array of Dehlinger to provide indicia that

would be useful in an array of capillaries. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, as stated above, Winkler clearly teaches reference indicia and the advantages of providing reference indicia i.e. reference indicia are essential for consistent and precise positionally addressable array construction and use (Column 18, line 51-Column 19, line 24). Dehlinger is interested in positional array construction (Abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the reference indicia of Winkler to the array construction of Dehlinger to thereby consistently and precisely construct arrays.

***Double Patenting***

*reiterated from previous office action*

11. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a **terminal disclaimer** **r cannot overcome a double patenting rejection** based upon 35 U.S.C. 101.

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12. Claims 1-10 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-10 of copending Application No. 09/790,321. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

**Response to Terminal Disclaimer**

13. Applicant's filing of a Terminal Disclaimer is acknowledged. However, as stated in the Office Action of 14 November 2002 and reiterated above, A statutory type double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope but cannot be overcome by filing a Terminal Disclaimer.

The above rejection is maintained.

14. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 31 March 2003 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### **Conclusion**

15. No claim is allowed.
16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.  
Primary Examiner  
Art Unit: 1634  
October 16, 2003